

STATE OF CALIFORNIA
FISH AND GAME COMMISSION
FINAL STATEMENT OF REASONS FOR REGULATORY ACTION

Amend subsections (a)(9) to Section 671.1
Title 14, California Code of Regulations
Re: Review of Transgenic Fish Permit Applications

- I. Date of Initial Statement of Reasons: March 5, 2003
- II. Date of Pre-adoption Statement of Reasons: May 16, 2003
- III. Date of Final Statement of Reasons: June 30, 2003
- IV. Dates and Locations of Scheduled Hearings:
 - (a) Notice Hearing: Date: April 4, 2003
Location: Visalia
 - (b) Discussion Hearing: Date: May 8, 2003
Location: Riverside
 - (c) Adoption Hearing: Date: June 20, 2003
Location: Mammoth Lakes
- V. Update:

No modifications were made to the originally proposed language of the Initial Statement of Reasons.
- VI. Summary of Primary Considerations Raised in Support of or Opposition to the Proposed Actions and Reasons for Rejecting those Considerations:

Responses to public comments received prior to May 8, 2003 were included in the Pre-adoption Statement of Reasons (see attached).

1. Senator Byron D. Sher, California Legislature, June 16, 2003, letter

Senator Sher reiterated his thoughts expressed in a previous letter by supporting the proposed regulation that requires public notification during the permitting process for transgenic species. However, the Senator continues to express concern about the lack of prohibition of commercial production of transgenic species for any reason.

Departments Response: The Department acknowledges Senator Sher's support for the proposed regulation.

The Senator's concern regarding existing regulations and the prohibition of transgenic species for any commercial purpose other than research has been addressed in previous documents and Commission meetings. The Department has previously indicated that commercial production for pharmaceutical or biomedical purposes performed in compliance with permitting requirements established in existing regulations would not pose a significant environmental risk.

2. Karen Reyna and Kate Wing, Ocean Conservancy, and Natural Resource Defense Council, June 13, 2003, letter.

Supported proposal as presented.

Departments Response: The Department acknowledges Ms. Reyna's and Ms. Wing's organizations' support for the proposed regulation.

3. Paul Weakland, June 20, 2003, oral testimony.

Mr. Weakland expressed opposition to any manipulation of natural species through genetic modification and the potential effects to native species if modified organisms escape to the wild. He also opposed any research using transgenic animals being performed in California.

Department Response: The Department recognizes the concerns and potential problems caused by the escape of transgenic aquatic animals. The current regulations along with this proposal are aimed at ensuring that facilities permitted to possess transgenic fish are secure and that the public has an opportunity to participate in the permitting process.

VII. Location and Index of Rulemaking File:

A rulemaking file with attached file index is maintained at:
California Fish and Game Commission
1416 Ninth Street
Sacramento, California 95814

VIII. Location of Department files:

Department of Fish and Game
1416 Ninth Street
Sacramento, California 95814

IX. Description of Reasonable Alternatives to Regulatory Action:

- (a) Alternatives to Regulation Change: None was identified.
- (b) No Change Alternative: Current regulations do not provide for a public review of permits issued by the Department for restricted transgenic fish.

Interested parties have expressed a desire to have the opportunity to review and comment on such permits in a public forum. Current regulations do not meet the demands of the majority of the interested public.

- (c) Consideration of Alternatives: In view of information currently possessed, no reasonable alternative considered would be more effective in carrying out the purposes for which the regulation is proposed or would be as effective and less burdensome than the proposed regulation.

X. Impact of Regulatory Action:

The potential for significant statewide adverse economic impacts that might result from the proposed regulatory action has been assessed, and the following initial determinations relative to the required statutory categories have been made:

- (a) Significant Statewide Adverse Economic Impact Directly Affecting Businesses, Including the Ability of California Businessmen to Compete with Businesses in Other States: The proposed action will not have a significant statewide adverse economic impact affecting businesses, including the ability of California businesses to compete with businesses in other states.
- (b) Impact on the Creation or Elimination of Jobs Within the State, the Creation of New Businesses or the Elimination of Existing Businesses, or the Expansion of Businesses in California: None.
- (c) Cost Impacts on Private Persons: The agency is not aware of any cost impacts that a representative private person would necessarily incur in reasonable compliance with the proposed action.
- (d) Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None.
- (e) Other Nondiscretionary Costs/Savings to Local Agencies: None.
- (f) Programs Mandated on Local Agencies or School Districts: None.
- (g) Costs Imposed on Any Local Agency or School District that is Required to be Reimbursed Under Part 7 (commencing with Section 17500) of Division 4: None.
- (h) Effect on Housing Costs: None.

Updated Informative Digest/Policy Statement Overview

Existing regulations (Section 671.1, Title 14, CCR) provide for the Department to issue permits, with conditions, to import, export, transport, maintain, dispose of, or use for any purpose any animal otherwise restricted by regulation, including transgenic aquatic animals, as defined.

The proposed regulatory action would require the Department to notify any interested party, who has requested that notification, upon receipt of an application for the issuance of such a permit for transgenic aquatic animals.

The proposed regulatory action would also require the Department to consider all written comments received regarding each such permit application prior to approving the permit.

The proposed regulatory action would require the Commission to review all applications approved by the Department at a regularly scheduled meeting and authorize the denial of the permit for specified cause.

The proposed regulatory action would require the Department and interested parties to complete a review of that portion of the regulations (subsection 671.1(a)(9)) specific to the issuance of permits for transgenic aquatic animals not later than May 14, 2004, and provide a summary of that review to the Commission at a regular meeting within 90 days of that date.

A minor editorial change was made to existing regulations in subsection 671.1(a)(9)(G) where an incorrect reference was discovered to a nonexistent subsection (671(b)6). The correct reference is 671.1(b)(6).

The Commission adopted the proposed regulations as proposed without changes.

Subsection (a) of Section 671.1, Title 14, California Code of Regulations, is amended to read:

§671.1. Permits for Restricted Species.

(a) General. It is unlawful for any person to import, export, transport, maintain, dispose of, or use for any purpose any animal restricted by Section 671 except as authorized in a permit issued by the department.

(1) Limited Scope. A permit issued pursuant to this Section 671.1 does not supersede any Federal, State, or local law regulating or prohibiting the animals or the activities authorized in the permit.

(2) Inspections. The department may approve an application prior to facilities being inspected and approved. A permit shall not be issued unless the applicant's facilities have been inspected and approved by the department or persons designated by the department.

The department may enter any facility at a reasonable hour, where restricted species are kept or may be kept to inspect animals, facilities, animal equipment, or to inspect, audit, or copy any permit, book or record required to be kept by these regulations or federal regulations relating to such species.

(3) Change of Address or Name. The permittee must notify the Department's License and Revenue Division, 3211 S Street, Sacramento, California 95816, in writing of any change of address or name related to the permit within fourteen (14) days of the change.

(4) Records. Any record, log, invoice, or other document required by this Section 671.1 shall be maintained by the permittee for at least three years from the date issued, and be made available to the department immediately upon demand.

(5) Transportation Records Required of Broker/Dealer. The permittee shall prepare and sign an invoice in duplicate prior to any animals leaving their facility. The invoice shall contain the name and address of the Broker/Dealer, a phone number where the Broker/Dealer and the consignee can be reached 24 hours, the name and address of the consignee, the date of the shipment, and the number and scientific name of each animal. The invoice shall accompany the animals being shipped. The consignee shall sign and date the invoice receipt of the shipment and retain a copy.

(6) Permits for Business. A person (as defined in Fish and Game Code Section 67) other than a natural person can qualify for and be issued a permit, only by employing at least one full time employee who possesses the requirements for obtaining a permit. The permittee must continue to employ such qualified persons as long as the animals are possessed in California.

(7) Financial Responsibility. The department may require an applicant for a nonresident permit to provide proof he/she will immediately cover all expenses incurred by the department for personnel, equipment, and facilities used to locate, capture, house, care for, and transport animals that escape or that are released or abandoned. The written proof must be in the form of an insurance bond or other financial guarantee payable to the department, local government agency, or entity contracting for the animals.

(8) Health Certificates. The department may require as a condition on any permit that restricted animals be approved for interstate shipment pursuant to applicable federal or state agency standards for diseases such as but not limited to tuberculosis, brucellosis, and pseudo rabies. Permit conditions may be more restrictive than federal standards.

(9) Transgenic Aquatic Animals. The department may issue permits for importation, possession, transportation or rearing of, or research on, transgenic aquatic animals pursuant to the following terms and conditions:

(A) All transgenic aquatic animals shall be held, raised, and transported in a closed-water system or in a system which treats effluent discharge from the facility with a disinfection system adequate to ensure against the inadvertent release of live animals. A closed-water system means that there is no discharge to waters of the state. Municipal treated sewage systems are not considered waters of the state. The Commission may grant an exception to subsection (a)(9)(A) of this regulation if it is determined that doing so shall not pose a significant risk to the waters or wildlife of the state.

(B) Access to facilities containing transgenic aquatic animals must be restricted through means determined to be adequate by the Department to assure against unauthorized removal of animals.

(C) Movement of live transgenic aquatic animals from facilities is prohibited unless specifically permitted by the Department.

(D) Release of transgenic aquatic animals or their progeny into waters of the state is prohibited.

(E) If transgenic aquatic animals are held with non-transgenic animals of the same species, all such animals that commingle with transgenic animals shall be treated as transgenic for the purposes of regulation and may not be introduced into waters of the state. Nontransgenic individuals that can be individually identified as nontransgenic may be exempt from this provision with prior department approval.

(F) In addition to any other penalty provided by law, any unauthorized release of transgenic aquatic animals or their progeny into the waters of the state may be subject to the penalties provided for under Fish and Game Code Sections 2125, 12007, and/or 12023

(G) A university, college, governmental research agency or other bona fide scientific institution, as determined by the department, may apply for an expedited permit review under ~~671(b)6~~ 671.1(b)(6) of this section by demonstrating that they meet or exceed the requirements stipulated in subsections (A) through (F) as part of a federal program or permit, for example, National Institute of Health guidelines administered by an Institutional Animal Care and Use Committee (IACUC). Such institutions shall have 120 calendar days from May 14, 2003 to submit supporting documentation for an initial permit.

(H) The Department shall provide written notice of the filing of all permit applications to any interested party who submits a written request for such notice. The Department shall consider all written comments regarding a permit application that are received from any interested party prior to approval of that application. All approved applications shall be reviewed by the Fish and Game Commission during a regularly scheduled public meeting; and the Commission, following public comment, may deny the issuance of a permit if it finds that an applicant is or will be unable to meet all regulatory requirements for importation, transportation, possession, and confinement of transgenic aquatic animals.

(l) The regulations under subsection 671.1(a)(9) shall be reviewed by the Department and other interested parties no later than one year after their effective date of May 14, 2003. A summary of the review shall be reported to the Commission at a regularly scheduled meeting within 90 days of May 14, 2004.

NOTE

Authority: Sections 1002, 2118, 2120, 2122, 2150, and 2150.2, Fish and Game Code.

Reference: Sections 2116-2118, 2190, and 2271, Fish and Game Code.

Attachment

Responses to public comments that were presented in the Pre-adoption Statement of Reasons of May 16, 2003

1. Senator Byron D. Sher, California Legislature, May 7, 2003, letter

Senator Sher expressed support for the proposed regulation that requires public notification during the permitting process for transgenic species. In addition, the Senator expressed concern about existing regulations that do not prohibit the commercial production of transgenic species for any reason.

Departments Response: The Department acknowledges Senator Sher's support for the proposed regulation.

The Senator's concern regarding existing regulations and the prohibition of transgenic species for any commercial purpose other than research has been addressed in previous documents and Commission meetings. The Department has previously indicated that commercial production for pharmaceutical or biomedical purposes performed in compliance with permitting requirements established in existing regulations would not pose a significant environmental risk.

2. Karen Reyna, Ocean Conservancy, and Natural Resource Defense Council, and David McHune, California Aquaculture Association, May 8, oral testimony.

Supported proposal as presented.

3. Paul Weakland, May 8, 2003, oral testimony.

Opposed to any work with transgenic species because of the potential danger to native species if transgenic animals escape. He cited general examples where aquaculture and research animals have caused problems with wild populations in the past.

Department Response: The Department recognizes the concerns and potential problems caused by the escape of transgenic aquatic animals. The current regulations along with this proposal are aimed at ensuring that facilities permitted to possess transgenic fish are secure and that the public has an opportunity to participate in the permitting process.

4. Rebecca Spector, Center for Food Safety, May 8, 2003, oral testimony.

Supported proposal, however, she requested a 90-day public review period before deciding on a permit, and a 30-day notice before a permit becomes effective. She also stated that her organization is willing to work with the Department to

determine an adequate review procedure.

Department Response: The current proposal requires the Department to provide written notice of the filing of all permit applications to any interested party requesting such information, and consider any comments received in the final permit-approval decision. All permits approved by the Department will be presented for additional public comment at a regularly scheduled Commission meeting before being issued. The Commission has the authority to deny any permit approved by the Department. Also, the Commission may choose to delay action on a permit until a subsequent meeting if additional public review is warranted. The Department considers the requested 90-day public review period excessive for applicants currently working under federal guidelines that meet or exceed the State's guidelines. However, for the relatively few expected applicants that are not working under federal guidelines, or those that create significant concern regarding environmental risk, the current proposal allows for additional time for public comments to be considered within the Commission process.

5. Patrick Sharp, UCLA, May 8, 2003, oral testimony.

Did not specifically state a position of support or non-support of the proposed regulation, however, several questions were presented regarding existing regulations pertaining to transgenic aquatic animals. Also, the presentation included a recommendation for exempting those species commonly being used in biomedical research from transgenic permits.

Department Response: Following the Commission's direction, Department staff has personally discussed with Dr. Sharp the questions he presented regarding the transgenic aquatic animal regulations. In addition, the Department acknowledges that some of the technical permit-processing concerns may not be fully addressed, and others may not be discovered, until the permit process has been implemented for a period of time. In order to fully address any potential problems associated with transgenic permits, the current proposal requires a summary review to be presented of the permitting process within 90 days after May 14, 2004.

Regarding exemption requests for certain species commonly used by biomedical researchers, the Department does not have adequate information to determine the level of environmental risk associated with a particular species that has undergone genetic modification. Until information is available to ensure that specific genetic manipulations have not created an increased level of environmental risk, exemptions requests will not be recommended by the Department.

5. Dallas Weaver, Scientific Hatcheries, May 8, 2003, oral testimony.

Dr. Weaver recommends that non-native research species, specifically zebrafish, should be exempted from the transgenic permitting process. He believes such an exemption would eliminate most of the permitting workload for the Department.

Department Response: See Department's response in Item No. 5 above.

6. Virginia Handley, Fund for Animals, May 8, 2003, oral testimony.

Recommends that transgenic aquatic animal permits be limited for research purposes only. She believes that transgenic aquatic animals will be released to the wild and cause environmental harm if grown by aquaculturists.

Department Response: This comment does not specifically address this proposal, rather it is concerned with current regulations. The Department has taken the position that the production of transgenic aquatic animals by aquaculturists should remain as a potential permitted activity if it presents acceptable environmental risks. If benefits to human health were discovered that required production of large quantities of transgenic animals, aquaculturists would be the producers of these animals.